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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,680	11/12/2003	Harshad Patel	LIFE-044CON	9066

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

A5

Office Action Summary	Application No.	Applicant(s)	
	10/712,680	PATEL ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 9-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *January 22, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprises". Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: On page 1 of the specification in the section entitled "Cross Reference to Related Applications", the word "copending" should be deleted, and the following phrase should be inserted after the phrase "filed March 14, 2002" so as to update the status of the parent application: --, now US Patent no. 6,682,933, issued on January 27, 2004--.

Appropriate correction is required.

4. Claims 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim 9 is indefinite since it refers to "a second set of criteria substantially as represented in Figure 4". This phrase renders the claim indefinite since the metes and bounds of the claim are not clear. Since Figure 4 is a graph plotting an X parameter versus a Y parameter to obtain two line functions, it is not clear whether the entire range for each of the X and Y parameters is included within the metes and bounds of claim 9, or whether only specific data points along the

lines depicted in Figure 4 are included within the metes and bounds of claim 9. In addition, it is unclear from Figure 4 how the line functions depicted therein are obtained. It is not normal U.S. practice to refer to drawings in the claims. Because of this and since the methods to obtain the line functions depicted in Figure 4 are described on page 10 of the instant specification, Applicants are required to remove the reference to figure 4 in claim 9, and replace it with the description of the relevant information that this figure represents, as disclosed on page 10 of the specification.

5. Claims 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 4 of claim 9, the abbreviation "PT" should be changed to –prothrombin (PT)—so as to provide the full meaning. Claim 9 is indefinite since it is unclear from the last step of comparing in the method how a test strip is qualified. The preamble of the claim recites a method for test strip qualification. However, none of the steps of the method recite how this is done. How does the comparison of the first control area to the first set of criteria and the comparison of the second control area to the second set of criteria serve to qualify a test strip?

On line 1 of claim 10, the phrase "are substantially comprise" does not make proper sense. In claim 10, the full meaning for the abbreviation "INR" should be provided in order to provide further clarification.

In claims 11, 13 and 14, it is suggested to change the phrase "made by a method selected from a group of methods consisting of the test strip qualification methods of claim 9 and 10" to –

made by a method selected from the test strip qualification methods of claim 9 or 10—so as to refer to claims 9 and 10 in the alternative only.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 9-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-12 of U.S. Patent No. 6,682,933. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method, a system and a computer readable medium for test strip qualification where a test strip having an assay reaction area, a first control area and a second control area is provided, prothrombin results for each reaction area are obtained, and the test

results from the first control area are compared to a first set of criteria and the test results from the second control area are compared to a second set of criteria in order to qualify the test strips. Since Figure 4 of the instant application depicts the description of the second control qualification criteria as recited in claims 5-12 of US patent no. 6,682,933, these sets of claims are obvious variants of one another.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Kermani who teaches of a method and system for determining the acceptability of signal data collected from a prothrombin time test strip. Kermani was filed after the effective filing date of the instant application.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

April 28, 2004

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP [redacted] 1700